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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,972	03/30/2006	Yasutaka Takada	127573	9934

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EXAMINER	
ROBINSON, BINTA M	
ART UNIT	**PAPER NUMBER**
1625	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,972	TAKADA ET AL.	
	Examiner	Art Unit	
	BINTA M. ROBINSON	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The 102 (b) rejections over Sakoda et. al. and over Matsumoto et. al. and the 103 (a) rejection over Sakoda over Brittain and Gogassy of claim 5, and the 103 (a) rejection over Matsumoto et. al. of claim 5 are withdrawn in light of applicant's amendments and remarks filed 1/30/09.

(amended rejections)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakoda et. al. as applied to claims 1-2, 6 above, and further in view of Brittain et. al. Sakoda et. al. teaches the process of obtaining the compound of formula 6 which reads on the instant final product, by recrystallizations of the compound of formula 6 to 100% enantiomeric purity from ethanol. See page 9, lines 3-5, the right column. The difference between the prior art process and the instantly claimed process is the that the prior art process involves dissolving a mixture of the compound of formula (1) in which one of the optically enantiomers is enriched in the solution and recrystallized from it versus the instant process which alternatively teaches a process consisting of dissolving a racemate of the compound of formula (1) in a solvent to prepare a supersaturated solution; and adding a crystal of either one of the optically active compounds of formula (1) as a seed crystal in the supersaturated solution to allow a crystal of one of the

optically active compounds added as the seed crystal to separate out. Brittain teaches that the instantly claimed process not taught in the prior art, is a conventional method of separating enantiomers from racemic mixtures. Brittain teaches that enantiomorphic crystals can be separated while formed simultaneously in a mother liquor which remains racemic. Seed crystals are obtained and are required for the direct crystallization to produce larger quantities of the resolved material. See page 687 of Brittain, second column. Brittain also teaches that when a compound forms a true racemate, that this compound can be formed via a derivatization reaction, wherein resolving agents are used to form dissociable diasteriomer species, wherein fractional crystallization is further used to purify the enantiomers. See the first and second columns of page 688 of Brittain under the section “Resolution of True Racemates". It would have been obvious to one of ordinary skill in the art to use conventional methods of resolution of racemates to produce the final instant product. Accordingly, the instant process is deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed process over those of the prior art process.

Claims 1-2, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et. al. as applied to claims 1-4 above, and further in view of Brittain et. al. Matsumoto et. al. teaches the instant process of obtaining the compound of formula 1 which reads on the instant final product, by recrystallizing the compound of formula 1 and improving the optical purity by this recrystallization of compounds of formula I of the (R) enantiomer by means of recrystallization in ethyl acetate or ethanol. See the second upper right column of page 5 and see compound 1 on page 2. The difference

between the prior art process and the instantly claimed process is that the prior art process involves dissolving a mixture of the compound of formula (1) in which one of the optically enantiomers is enriched in the solution and recrystallized from it versus the instant process which alternatively teaches a process consisting of dissolving a racemate of the compound of formula (1) in a solvent to prepare a supersaturated solution; and adding a crystal of either one of the optically active compounds of formula (1) as a seed crystal in the supersaturated solution to allow a crystal of one of the optically active compounds added as the seed crystal to separate out. Brittain teaches that the instantly claimed process not taught in the prior art, is a conventional method of separating enantiomers from racemic mixtures. Brittain teaches that enantiomorphic crystals can be separated while formed simultaneously in a mother liquor remains which racemic. Seed crystals are obtained and are required for the direct crystallization to produce larger quantities of the resolved material. See page 687 of Brittain, second column. Brittain also teaches that when a compound forms a true racemate, that this compound can be formed via a derivatization reaction, wherein resolving agents are used to form dissociable diasteriomer species, wherein fractional crystallization is further used to purify the enantiomers. See the first and second columns of page 688 of Brittain under the section “Resolution of True Racemates". It would have been obvious to one of ordinary skill in the art to use conventional methods of resolution of racemates to produce the final instant product. Accordingly, the instant process is deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed process over those of the prior art process.

(Response to Applicant' Remarks)

The applicant alleges that the 103 (a) rejections above are improper because it is alleged that the Brittain et. al. reference does not disclose conventional methods in the art for the resolution of racemates, but only applies to the resolution of conglomerates. However, this is not so. On page 687, in the left hand column, the heading reads "Resolution of Enatiomer Mixtures" - Resolution of conglomerates is only a "subheading" under this generic category. Additionally, the applicant does not state in the specification or in the claims, that the claimed compound products can not be conglomerates. The applicant also claims unexpected results for claim 6, for the first time which were not disclosed in the specification or anywhere else in the application. However, under 37 CFR 1.132, when any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section. Since the claims were rejected to and the applicant's submitted claim 6 with new limitations and claiming unexpected results, this evidence must be provided by way of an oath or declaration under this section.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Janet Andres can be reached on 571-272-0670.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703305-3592, and (703305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

/Binta M Robinson/
Examiner, Art Unit 1625

/Janet L. Andres/
Supervisory Patent Examiner, Art Unit 1625